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EXAMINER

OLSON, ERIC

ART UNIT

PAPER NUMBER

1623

NOTIFICATION DATE

DELIVERY MODE

02/09/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/572,664 | <b>Applicant(s)</b><br>RHOADES ET AL. |  |
|                              | <b>Examiner</b><br>ERIC S. OLSON     | <b>Art Unit</b><br>1623               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-30 is/are pending in the application.
- 4a) Of the above claim(s) 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-21, 23-26 and 28-30 is/are rejected.
- 7) ☒ Claim(s) 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **Detailed Action**

This office action is a response to applicant's communication submitted October 28, 2008 wherein claims 12-26 and 28-30 are amended. This application is a national stage application of PCT/EP04/10496, filed September 17, 2004, which claims priority to foreign application GB0321996.1, filed September 19, 2003.

Claims 12-30 are pending in this application. Claim 27 is withdrawn from consideration as being directed to a non-elected invention.

Claims 12-26 and 28-30 as amended are examined on the merits herein.

Applicant's amendment, submitted October 28, 2008, with respect to the rejection of instant claims 18, 21, and 27-29 under 35 USC 101 for reciting a use without setting forth any particular method steps, has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to recite a proper method. Therefore the rejection is withdrawn.

Applicant's amendment, submitted October 28, 2008, with respect to the rejection of instant claims 18, 21, and 27-29 under 35 USC 112, second paragraph, for reciting a use without setting forth any particular method steps, has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to recite a proper method. Therefore the rejection is withdrawn.

Applicant's amendment, submitted October 28, 2008, with respect to the rejection of instant claim 24 under 35 USC 112, second paragraph, for containing a broad limitation followed by a narrow limitation, has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to remove the broad limitation. Therefore the rejection is withdrawn.

Applicant's amendment, submitted October 28, 2008, with respect to the rejection of instant claims 12-23 and 28-30 under 35 USC 112, first paragraph, for lacking enablement for preventative methods, has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to no longer claim preventative methods. Therefore the rejection is withdrawn.

Applicant's amendment, submitted October 28, 2008, with respect to the rejection of instant claims 12-26 and 28-30 under 35 USC 112, first paragraph, for lacking enablement for methods of treating all pathogenic infectious agents, has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to only include enteric bacterial infections. Therefore the rejection is withdrawn.

Applicant's amendment, submitted October 28, 2008, with respect to the rejection of instant claims 12-14, 16-22, 25, 26, and 28-30 under 35 USC 102(b) for being anticipated by Guggenbichler et al., has been fully considered and found to be

Art Unit: 1623

persuasive to remove the rejection as the claims have been amended to no longer include oligogalacturonides and pectic oligosaccharides. Therefore the rejection is withdrawn.

Applicant's amendment, submitted October 28, 2008, with respect to the rejection of instant claims 12-14 and 16-18 under 35 USC 102(b) for being anticipated by Akiyama et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to no longer include curdlan. Therefore the rejection is withdrawn.

Applicant's amendment, submitted October 28, 2008, with respect to the rejection of instant claims 12-14 and 16-18 under 35 USC 102(a) for being anticipated by Martin-Sosa et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to no longer include sialylated oligosaccharides. Therefore the rejection is withdrawn.

Applicant's amendment, submitted October 28, 2008, with respect to the rejection of instant claims 19-22, 25, 26, and 28-30 under 35 USC 103(a) for being anticipated by Martin-Sosa et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to no longer include sialylated oligosaccharides. Therefore the rejection is withdrawn.

The following new grounds of rejection are introduced:

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 12-14, 16-18, 25, 26, and 28-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Einarsson et al. (PCT international publication WO03/026677, reference included with PTO-892)

Einarsson et al. discloses compositions comprising chito-oligosaccharides. (p. 8 lines 16-23) These compositions can contain pharmaceutically acceptable excipients, flavoring substances, nutrients, or colorants. (p. 11 line 25 - p. 12 line 7) Thus these compositions are reasonably considered to be a “nutritional or pharmaceutical composition,” according to the instant claims. Einarsson et al. also discloses a use of chito-oligosaccharides in the manufacture of a medicament. (p. 13 lines 32-34) Example 3 on p. 17 line 17 - p. 18 line 19 discloses a method comprising administering these chito-oligosaccharide compositions to a subject. Although Einarsson et al. does not explicitly disclose compositions for inhibiting or treating enteral infections of pathogenic bacteria, this property is inherent in any composition containing the recited ingredients.

Art Unit: 1623

Furthermore administering said compositions to a subject inherently reduces and inhibits invasion or infection of said pathogenic bacteria in any mammal it is administered to, as said mammal will have a reduced likelihood of contracting an enteric bacterial infection. Therefore Einarsson et al. anticipates the claimed invention.

Claims 12-14, 16-18, 25, 26, and 28-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Takaichi et al. (US patent 6750331, cited in PTO-892)

Takaichi et al. discloses compositions comprising oligosaccharides including lactosucrose, isomaltooligosaccharide, gentiooligosaccharide, mannoooligosaccharide, or chitooligosaccharide. (column 2 lines 5-24) These compositions can contain other ingredients such as foaming agents, neutralizing components, and fiber which are pharmaceutically acceptable excipients. (Column 2 lines 28-42) Lactose can also be added as an additional additive. (column 5 line 29) Thus these compositions are reasonably considered to be a "nutritional or pharmaceutical composition," according to the instant claims. Takaichi et al. also discloses methods of making medicaments from these compounds. (column 5 lines 49-55, column line 20 - column 8 line 10) These compositions can be administered to a subject to increase intestinal bifidobacteria levels. (column 3 lines 1-28) Although Takaichi et al. does not explicitly disclose compositions for inhibiting or treating enteral infections of pathogenic bacteria, this property is inherent in any composition containing the recited ingredients. Furthermore administering said compositions to a subject inherently reduces and inhibits invasion or infection of said pathogenic bacteria in any mammal it is administered to, as said

Art Unit: 1623

mammal will have a reduced likelihood of contracting an enteric bacterial infection.

Therefore Takaichi et al. anticipates the claimed invention.

Claims 12-14, 16-18, 24, 25, and 28-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Bindels et al. (US patent 6863918, cited in PTO-892)

Bindels et al. discloses an infant formula. (column 2 lines 47-54) One component of the infant formula is a prebiotic component such as lactosucrose, mannose-based oligosaccharides, arabino-oligosaccharides, isomalto-oligosaccharides, and possibly lactose. (column 15 lines 23-36) In one preferred embodiment, these oligosaccharides have between 2-20 sugar residues and connected by alpha-1,6 linkages. (column 15 lines 16-22) Examples are given for these compositions and methods of making them. (column 16 line 60 - column 18 line 59) A study is also disclosed in which infants were fed the disclosed formula, resulting in a decrease in symptoms such as constipation, abdominal discomfort, and minor gastrointestinal problems. (column 18 line 65 - column 19 line 7) Although Bindels et al. does not explicitly disclose compositions for inhibiting or treating enteral infections of pathogenic bacteria, this property is inherent in any composition containing the recited ingredients. Furthermore administering said compositions to a subject inherently reduces and inhibits invasion or infection of said pathogenic bacteria in any mammal it is administered to, as said mammal will have a reduced likelihood of contracting an enteric bacterial infection. Therefore Bindels et al. anticipates the claimed invention.



Claims 12-14, 16-18, 25, and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Tuohy et al. (Reference included with PTO-892)

Tuohy et al. discloses a study of the effects of PHGG (partially hydrolyzed guar gum) and FOS (fructooligosaccharide) on gut microflora in humans. (p. 342, right column second paragraph 0 p. 343 right column first paragraph) This study constitutes a method comprising administering PHGG to subjects according to the instant claims. Furthermore the prebiotics were supplied as biscuits which are reasonably considered to be a pharmaceutical or nutritional composition according to the claimed invention. Subjects receiving the prebiotic treatment increased the levels of *bifidobacterium* in their intestines. (p. 344, left column and tables 1 and 2) Although Tuohy et al. does not explicitly disclose compositions for inhibiting or treating enteral infections of pathogenic bacteria, this property is inherent in any composition containing the recited ingredients. Furthermore administering said compositions to a subject inherently reduces and inhibits invasion or infection of said pathogenic bacteria in any mammal it is administered to, as said mammal will have a reduced likelihood of contracting an enteric bacterial infection. Therefore Tuohy et al. anticipates the claimed invention.

Claims 12-14, 16-18, 25, and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Nesser et al. (PCT international publication WO00/49885, Reference included with PTO-892)

Nesser et al. discloses a composition and method for prevention or treatment of a bone or dental disorder comprising a milk protein hydrolysate. (p. 5 line 30 - p. 6 line

Art Unit: 1623

3) The milk protein hydrolysate preferably comprises a caseinoglycomacropeptide. (p. 6 lines 12-17) This composition is reasonably considered to be a pharmaceutical or nutritional composition according to the instant claims. It can be incorporated into a food formulation, which would comprise a nutritionally acceptable excipient. (p. 7 ,lines 4-18) Pp. 16-18 disclose methods of making pharmaceutical or nutritional compositions comprising adding to the composition the disclosed caseinoglycomacropeptide.

Although Nesser et al. does not explicitly disclose compositions for inhibiting or treating enteral infections of pathogenic bacteria, this property is inherent in any composition containing the recited ingredients. Furthermore administering said compositions to a subject inherently reduces and inhibits invasion or infection of said pathogenic bacteria in any mammal it is administered to, as said mammal will have a reduced likelihood of contracting an enteric bacterial infection. Therefore Nesser et al. anticipates the claimed invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tuohy et al. (Reference included with PTO-892) as applied to claims 12-14, 16-18, 25,

Art Unit: 1623

and 28-30 above, and further in view of Prieto et al. (US patent 5906982, cited in PTO-892)

The disclosure of Tuohy et al. is discussed above. Tuohy et al. does not disclose a method comprising administering the disclosed composition to a subject suffering from a pathogenic bacteria-associated enteric disorder.

Prieto et al. discloses a nutritional formulation that is effective for stimulating the growth of bacteria of the genus *Bifidobacterium*. (column 2 lines 1-13) This formulation can be used to inhibit infection with bacterial species such as *Bacteroides*, *Clostridium*, and *E. coli*. (column 4 lines 5-15)

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer the biscuits described by Tuohy et al. to a patient suffering from an enteric bacterial infection. One of ordinary skill in the art would have been motivated to do so because Prieto et al. already discloses using a different *Bifidobacterium*-enhancing prebiotic composition for the same purpose. One of ordinary skill in the art would reasonably have expected success because it is well recognized in the art that one known composition can be substituted for another known composition having the same disclosed function and utility.

Therefore the invention taken as a whole is *prima facie* obvious.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bindels et al. (US patent 6863918, cited in PTO-892)

The disclosure of Bindels et al. is discussed above. Bindels et al. does not explicitly disclose a composition comprising a mannose oligosaccharide comprising alpha-1,6 linkages.

It would have been obvious to one of ordinary skill in the art at the time of the invention to make the compositions of Bindels et al. using alpha-1,6-Manno-oligosaccharides. One of ordinary skill in the art would have been motivated to do so because Bindels et al. already discloses manno-oligosaccharides and discloses that alpha-1,6 linkages are preferred. One of ordinary skill in the art would reasonably have expected success because all of the required limitations are already disclosed by Bindels et al.

Therefore the invention taken as a whole is *prima facie* obvious.

Claims 19-21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bindels et al. (US patent 6863918, cited in PTO-892) as applied to claims 12-18, 25, and 28-30 above, and further in view of Reid et al. (US patent 5906982, cited in PTO-892)

The disclosure of Bindels et al. is discussed above. Bindels et al. does not disclose a method comprising administering the disclosed composition to a subject suffering from a pathogenic bacteria-associated enteric disorder.

Reid et al. discloses probiotic therapies for the treatment and inhibition of intestinal infection in newborns. (column 2 lines 47-59) Probiotic organisms having this beneficial effect include bacteria of the genus Bifidobacteria. (column 3 lines 8-19)

Art Unit: 1623

Infections that can be reduced or eliminated in this manner include bacterial pathogens such as *Clostridium*, *Escherichia*, *Kelbsiella*, *Salmonella*, *Shigella*, *Campylobacter*, *Pseudamonas*, *Streptococcus*, *Enterococcus*, *Staphylococcus*, and other species.

(column 4 lines 10-19) These species are infectious agents in infectious diarrhea among infants. (column 1 lines 27-42)

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer the infant formula described by Bindels et al. to a newborn suffering from an enteric bacterial infection. One of ordinary skill in the art would have been motivated to do so because Reid et al. already discloses treating the same disorders by improving the population of bifidobacteria in the intestine. The two therapies, the probiotic therapy of Reid et al. and the prebiotic therapy of Bindels et al. are directed toward producing the same effect (increased bifidobacterial population) in the same subject population. (infants) One of ordinary skill in the art would reasonably have expected success because it is well recognized in the art that one known composition can be substituted for another known composition having the same disclosed function and utility.

Therefore the invention taken as a whole is *prima facie* obvious.

The following rejections of record in the previous office action are maintained:

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1623

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 13, 16-20, and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Baillon et al. (PCT international publication WO01/65949, of record in previous action)

Baillon et al. discloses a method of treating pathogenic bacteria in an animal by administering a non-digestible carbohydrate. (p. 3 lines 21-23) Non-digestible carbohydrates include galactooligosaccharide and lactosucrose. (p. 4 lines 1-6) Pathogenic bacteria that can be treated in this manner include *Campylobacter jejuni*, *Clostridium*, *Salmonella*, and pathogenic *Escherichia coli*. (p. 6 lines 23-27) These pathogens cause various symptoms including diarrhea. (p. 1 line 12 - p. 2 line 24) Therefore the compositions comprise the same ingredients as the instant claims and the methods comprise administering the same ingredients to the same subjects. For these reasons Baillon et al. anticipates the claimed invention.

Response to Argument: Applicant's arguments, submitted October 28, 2008, with respect to the above grounds of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that the reference fails to disclose any of the claimed compounds. However, the reference discloses lactosucrose, which is still included in the invention as claimed. Therefore the rejection is maintained.

Claims 12-17 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Yokoyama et al. (Reference of record in previous action)

Yokoyama et al. discloses the synthesis of alpha 1-6 manno-oligosaccharides in a membrane fraction of *M. segmentis*. (p. 21622 paragraph 4 – p. 21623 paragraph 2)  
This oligosaccharide product is reasonably considered to be a pharmaceutical or nutritional composition according to the instant claims as it could be administered to a subject to produce a therapeutic effect. Therefore Yokoyama et al. anticipates the claimed invention. Note that claim 24 is given its broadest reasonable interpretation, namely as including all manno-oligosaccharides and methyl manno-oligosaccharides.

Response to Argument: Applicant's arguments, submitted October 28, 2008, with respect to the above grounds of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that the reference fails to disclose a nutritional or pharmaceutical composition. However, the limitation "nutritional or pharmaceutical composition" is an extremely broad limitation encompassing all compositions that could be administered to a human subject. The manno-oligosaccharides disclosed by Yokoyama et al. could be administered to a human subject, and therefore inherently possess the property of being a pharmaceutical or nutritional composition. Therefore the rejection is maintained.

### **Conclusion**

Claims 12-21, 23-26, and 28-30 are rejected. Claim 22 is objected to for depending from a rejected base claim but would be allowable if rewritten in independent

Art Unit: 1623

form incorporating all the limitations of the rejected base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/  
Examiner, Art Unit 1623  
2/2/2009